TITLE: Expedited Review Process

1.0 PURPOSE

This Standard Operating Procedure (SOP) sets forth the policies and procedures the VA Central IRB uses in evaluating projects to ensure they meet the eligibility criteria for the expedited review process. It also sets forth the procedures VA Central IRB members and the VA Central IRB administrative staff use in processing and performing the expedited reviews.

2.0 REVISION HISTORY

Initial Approval Date	August 4, 2008
Revision Dates	September 4, 2009 September 24, 2009 March 24, 2010

3.0 SCOPE

This Standard Operating Procedure applies to all VA Central IRB members and to VA Central IRB administrative staff involved in the determination of whether a project meets the eligibility criteria for expedited review and in the processing of projects using the expedited review process as detailed in this SOP.

4.0 POLICY

4. 1 It is the policy of the VA Central IRB that the expedited review procedure cannot be used if the research meets one or more of the following criteria:

4.1.1 The research poses more than minimal risk to human participants, as defined in paragraph 5.5 of this SOP.

4.1.2 The research is classified.

4.1.3 The identification of the participants and/or their responses would reasonably place the subjects at risk of criminal or civil liability or be damaging to the participants financial standing, employability, insurability, reputation, or be stigmatizing. An exception can be made when reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

4.1.4 Projects in which some or all of the participants are recruited from vulnerable populations as described in SOP 106, paragraph 4.2, are initially reviewed by the convened VA Central IRB and are not reviewed under expedited review procedures, even if the project otherwise qualifies for expedited review.

4.2 It is the policy of the VA Central IRB that the expedited review procedure may be used for newly submitted projects if the project does not meet any of the criteria in 4.1 above, and meets one or more of the following research categories as detailed by the Office of Human Research Protections (OHRP). If the research involves no more than minimal risk, one or more of the following categories apply regardless of the age of the participants, except as noted.

4.2.1 Category 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

4.2.2 Category 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture that meet one of the following criteria:

(a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.

(b) From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

4.2.3 Category 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples are as follow:

(a) Hair and nail clippings in a nondisfiguring manner

(b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction

(c) Permanent teeth if routine patient care indicates a need for extraction

(d) Excreta and external secretions (including sweat)

(e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue

(f) Placenta removed at delivery

(g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor

(h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques

(i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings

(j) Sputum collected after saline mist nebulization

4.2.4 Category 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Projects intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including projects of cleared medical devices for new indications.) Examples are as follow:

(a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy

(b) Weighing the participant or testing sensory acuity

(c) Magnetic resonance imaging

(d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography

(e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

4.2.5 Category 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as for medical treatment or diagnosis). This category refers only to research that is not exempt.

4.2.6 Category 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

4.2.7 Category 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

4.3 It is the policy of the VA Central IRB that continuing review of projects may be conducted via an expedited review process if the study meets one of the following criteria:

4.3.1 Continuing research activities pose no more than minimal risk to participants, the research met the criteria for expedited review at the time of initial submission of the study for review, and all procedures continue to meet at least one of the expedited review categories 1 through 7 above.

4.3.2 Category 8. Research that was previously reviewed by the convened IRB but meets one of the following categories:

(a) Where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants.

(b) Where no participants have been enrolled and no additional risks have been identified

(c) Where the remaining research activities are limited to data analysis

4.3.3 Category 9. Continuing review of research that was previously reviewed by the convened VA Central IRB, that is not conducted under an investigational new drug application or investigational device exemption, where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

4.4 It is the policy of the VA Central IRB that an expedited review procedure may be used to review amendments (modifications) to previously approved research during the period (one year or less) for which approval is authorized as follows:

4.4.1 Modifications to projects previously approved by the convened VA Central IRB may be reviewed via an expedited review process if they do not pose an increased risk to participants and the modifications constitute a minor change to previously approved research.

4.4.2 Modifications to projects previously approved by the VA Central IRB under the expedited review process may be reviewed via expedited review if the research continues to pose no more than minimal risk to human participants and the modifications do not involve any procedures that do not meet the expedited review categories 1 through 7.

4.4.3 Examples of minor changes that can be reviewed under the expedited review process include but are not limited to:

- Administrative changes
- Minor consent form changes
- Minor changes to recruitment procedures, recruitment materials, or submission of new recruitment materials to be used in accordance with approved recruitment methods
- Minor changes to project documents such as surveys, questionnaires, or brochures
- New project documents to be distributed to or seen by participants that are similar in substance to those previously approved
- Changes in payment to participants or the amount participants are paid that are not significant enough to affect the risk/benefit ratio of the project
- A decrease in the number and volume of specimen collections as long as they do not negatively affect the risk/benefit ratio or scientific methodology of the project
- Editorial changes that clarify but do not alter the existing meaning of a document
- Additions of or changes in project personnel as long as their qualifications are similar to any personnel who previously participated in the project
- Addition or deletion of a site as long as the total number of participants to be enrolled remains the same.

4.5 Changes to previously approved projects that were reviewed at a VA Central IRB convened meeting that generally **cannot** be reviewed via the expedited review process as a minor change are those that are directly related to the determinations that must be made by the VA Central IRB in approving a project. These include but are not limited to the following:

- Changes that adversely affect the risk/benefit ratio of the project or specifically increase the risk to participants
- Changes in inclusion/exclusion criteria that impact the risk/benefit ratio of the project
- Significant changes in project design, such as the addition of a new participant population or the elimination of a project arm
- New risk information that is substantial or adversely affects the risk/benefit ratio of the project
- Significant changes to the project documents to be distributed to or seen by participants

- New project documents to be distributed to or seen by participants that include information or questions that are substantively different from materials already approved by the IRB
- An increase or decrease in the number of project participants to be enrolled

4.6 It is the policy of VA Central IRB that only experienced scientific voting members of the VA Central IRB are authorized to perform reviews using the expedited process. An experienced member is one who has served on the VA Central IRB for at least six months and has been assigned as a Primary Reviewer on at least one study that has been reviewed at a convened meeting. A master letter signed by the VA Central IRB Co-Chairs which designates the VA Central IRB members authorized to perform expedited reviews is kept on file and is updated annually.

4.6.1 The VA Central IRB uses a two step review process for expedited review to ensure consistency in the conduct of the reviews among the designated voting members who serve as Reviewers. One of the VA Central IRB Co-Chairs, with the assistance of the VA Central IRB Administrator, will assign a voting scientific member to be the Expedited Reviewer. The Expedited Reviewer will be selected from the master letter kept on file in the VA Central IRB Administrative Office based on the member's expertise, experience on the IRB, and workload. That member will then provide an approval recommendation to the Co-Chair. The Co-Chair will then provide the final approval determination. The Expedited Reviewer and Co-Chair can exercise all the authorities of the VA Central IRB except that they may not disapprove the research.

4.6.2 The two step review process will also be used for continuing review. If available, the Expedited Reviewer who conducted the initial review will also conduct the continuing review and provide an approval recommendation to the Co-Chair concerning the PI/SC Application, the Local Site Investigator Applications, and any amendment to that application as long as the amended application still meets the criteria for expedited review. If the original Expedited Reviewer is not available, the Co-Chair will appoint another voting member to be a Reviewer. The expiration date of the continuing approval for both the PI/SC Application and all the Local Site Applications that were part of the continuing review package, is the date the Co-Chair approved the PI/SC Application.

4.6.3 For minor amendments to studies that were initially approved at a convened VA Central IRB meeting, the Expedited Reviewer will conduct the expedited review, make an approval recommendation to the Co-Chair, and the Co-Chair will make the final approval determination and sign the approval letter.

4.7 Although the research may be eligible for review using an expedited procedure, if the Co-Chair or Expedited Reviewer decides the research should be reviewed at a convened meeting, the VA Central IRB Coordinator will schedule the research for review at a convened meeting of the VA Central IRB.

4.8 The standard requirements for informed consent, or its waiver or alteration, that apply to review by the convened IRB, also apply to the expedited review process.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 The Expedited Reviewer is responsible for determining if a project is eligible for expedited review. If the Expedited Reviewer determines the project is eligible based on one of the nine approved categories, the Expedited Reviewer then conducts the expedited review in accordance with the procedures set forth in this SOP. The Expedited Reviewer must ensure that all IRB approval criteria are met prior to granting approval to a study under this process.

6.2 The VA Central IRB administrative staff is responsible for the following:

6.2.1 The VA Central IRB Coordinator makes an initial determination as to whether the project is eligible for expedited review and prepares all required documentation for the Expedited Reviewer to conduct the review. The VA Central IRB Coordinator also assists the Co-Chair or the designated Expedited Reviewer as needed in communicating any concerns or questions to the investigator that arise during the review process and prepares all VA Central IRB decision documents for signature of the Co-Chair. Upon completion of the process the VA Central IRB Coordinator maintains all documentation concerning the review and approval process and ensures all VA Central IRB tracking logs are updated.

6.2.2 The VA Central IRB Administrator is responsible for assisting the Co-Chairs in assigning qualified VA Central IRB voting members to perform the expedited reviews. The VA Central IRB Administrator also ensures that all projects approved under the expedited review process are reported to the convened VA Central IRB at the next regularly scheduled meeting.

6.3 Investigators are responsible for submitting complete and accurate information to the VA Central IRB using approved VA Central IRB forms, whether the submission is for a new project, an amendment, or continuing review. If the submission pertains to a new project, investigators must also complete the VA Central IRB Form 127, Request for Expedited Review of New Project, in accordance with SOP 104, Application Requirements for New Projects Sponsored by the Office of Research and Development (ORD) Services, if the project is to be considered for the expedited review process.

7.0 PROCEDURES

7.1 Initial Review by VA Central IRB Administrative Staff. The VA Central IRB Administrator receives all PI/SC New Project Applications, regardless of whether they qualify for review utilizing expedited review procedures or require review by the

convened VA Central IRB. Upon assignment of a VA Central IRB Coordinator to the project the following actions are taken:

7.1.1 The VA Central IRB Coordinator performs the following:

7.1.1.1 Upon receipt of new project documents, whether the documents pertain to a new project application, local site investigator applications, a continuing review report, or an amendment, the VA Central IRB Coordinator makes an initial determination as to whether the research is eligible for expedited review in accordance with the eligible categories detailed in paragraph 4 of this SOP. If the VA Central IRB Coordinator determines that the research is eligible for expedited review, sections 1 and 2 of VA Central IRB Form 121, Expedited Review Eligibility Determination (Attachment 1), are completed by the Coordinator.

7.1.1.2 In addition, the VA Central IRB Coordinator completes the applicable administrative screening checklist depending upon whether the documents pertain to a new project application, new local site investigator applications, or a continuing review request. An administrative screening checklist is not used for amendments. The screening checklists for PI/SC New Project Applications and for Continuing Reviews are forwarded to the VA Central IRB Administrator for review.

7.1.1.3 If the documents pertain to continuing review or new local site investigator applications, the VA Central IRB Coordinator prepares comparison tables of the approved PI/SC model documents and/or previously approved local site documents as applicable for use by the Reviewers in performing the review.

7.1.2 The VA Central IRB Administrator performs the following:

7.1.2.1 The screening checklists for all new project PI/SC Applications and all continuing review applications (both PI/SC and LSI Applications) are reviewed for completeness and accuracy. Any discrepancies are resolved prior to the VA Central IRB Administrator signing off on the document and sending it back to the VA Central IRB Coordinator to process for expedited review.

7.1.2.2 The VA Central IRB Administrator also consults with one of the Co-Chairs concerning the appointment of an Expedited Reviewer or multiple reviewers if required. Reviewers are assigned based on their scholarly or scientific expertise.

7.1.2.2.1 For the initial review of a new project, only one Expedited Reviewer will be designated.

7.1.2.2.2 For continuing reviews and the initial review of local site investigator applications, the Reviewer assigned will be the same reviewer as was assigned for the initial project. The VA Central IRB Coordinator will consult with the Reviewer and, depending upon the workload, the Expedited Reviewer can elect to

conduct the initial review in its entirety or request the designation and assistance of additional Reviewers.

7.1.2.2.3 If the Co-Chair determines that the assistance of an ad hoc consultant is required, the VA Central IRB Administrator will arrange for review by a qualified consultant. If no qualified ad hoc consultant is available, the Director, PRIDE will assist in recruiting a qualified consultant. The ad hoc consultant is sent the applicable project documentation, as well as the applicable reviewer checklist. Upon receipt of the ad hoc consultant's report, it will be forwarded by the VA Central IRB Coordinator to the applicable Co-Chair or designated Expedited Reviewer, along with the other project documentation.

7.1.3 The VA Central IRB Administrator does not review the screening checklists for the initial review of Local Site Investigator Applications that are undergoing expedited review, nor any amendments that qualify for expedited review. These are submitted directly to the applicable IRB Coordinator. However, any significant administrative issues that might need the attention of the VA Central IRB Administrator should be brought to his/her attention by the VA Central IRB Coordinator prior to processing these actions for review.

7.1.4 After the review is complete by the VA Central IRB Administrator, if required, the VA Central IRB Coordinator forwards the VA Central IRB Form 121, all project documents, the applicable Reviewer checklist depending upon the type of action being reviewed, and the standard Expedited Review Instructions (Attachment 2), to the selected Expedited Reviewer(s) or the Co-Chair as applicable.

7.1.4.1 All applicable documents are uploaded into an Expedited Reviewer folder for the study on the VA Central IRB SharePoint site. All documents are clearly named and organized by the VA Central IRB Coordinator for ease of reference by the Expedited Reviewer(s). The Expedited Reviewer(s) is then sent an e-mail by the VA Central IRB Coordinator indicating the documents are ready for review and providing the link to the applicable SharePoint folder.

7.1.4.2 If the documents pertain to the initial or re-review of a new project, the VA Central IRB Privacy Officer Representative and the Information Security Officer Representative, are also notified of the review request and provided the link. The applicable certification forms for their completion are also uploaded to the Reviewer folder on SharePoint.

7.1.4.3 If the documents pertain to a continuing review, the VA Central IRB Coordinator ensures a complete copy of the currently approved project, to include copies of previous amendment requests, continuing review reports, and any other reports have been uploaded to SharePoint. The VA Central IRB Coordinator may also make arrangements for the Expedited Reviewer to review all documents in person in the VA Central IRB Administrative Office if this is the preference of the Expedited Reviewer based on the volume of documentation that must be reviewed.

7.1.4.4 If the documents pertain to an amendment, all applicable documents pertaining to the amendment that are affected by the amendment request are uploaded to SharePoint.

7.2 Eligibility Determination. Upon receipt of the project documents, the assigned Expedited Reviewer or Co-Chair determines whether he/she has a conflict of interest. If the Reviewer does have a conflict, he or she completes the conflict of interest declaration on the applicable checklist as described in paragraph 7.3.1 and returns the checklist to the VA Central IRB Administrative Office. The Expedited Reviewer, or Co-Chair as applicable, makes the final eligibility determination and completes the VA Central IRB Form 121 by taking one of the following actions:

7.2.1 Agrees with the initial expedited review eligibility determination and the designated expedited review category as made by the VA Central IRB Coordinator.

7.2.2 Determines that the research is eligible for expedited review but changes the eligible category of review under which the research is eligible.

7.2.3 Determines that the research is not eligible for expedited review and that it must be reviewed at a convened meeting of the VA Central IRB. If this action is taken, the VA Central IRB Coordinator is notified immediately via phone or encrypted e-mail. The VA Central IRB Coordinator notifies the investigator and schedules the project for review at the next scheduled meeting of the IRB. The VA Central IRB Form 121 is signed and returned to the VA Central IRB Administrative Office via fax, encrypted e-mail, or uploaded to SharePoint by the Reviewer.

7.2.4 Determines that the research is exempt. If this determination is made, the VA Central IRB Coordinator is notified immediately via phone or e-mail. The VA Central IRB Form 121 is signed and returned to the VA Central IRB Administrative Office via fax, encrypted e-mail, or uploaded to SharePoint by the Reviewer The VA Central IRB Coordinator notifies the investigator that the project must be re-submitted in accordance with VA Central IRB SOP 107, Requests for Exemption Review and Determination.

7.3 Conduct of Expedited Review. The Expedited Reviewer reviews the project documentation and ensures that the research meets all the required VA Central IRB approval criteria as specified in VA Central IRB SOP 101, VA Central IRB Authorities, Responsibilities, and Activities by accomplishing the following:

7.3.1 The Expedited Reviewer completes one or more of the following checklists depending upon the type of documents being reviewed:

- VA Central IRB Form 111a, Reviewer Checklist PI New Project Application
- VA Central IRB Form 111b, Reviewer Checklist for Local Site Investigator Applications
- VA Central IRB Form 114a, Continuing Review Checklist for Local Site Investigator Applications

- VA Central IRB Form 114b, Reviewer Checklist for Continuing Review (PI/SC Application)
- VA Central IRB Form 120, Reviewer Checklist for Amendments

These are the same checklists used by reviewers for presenting research at the convened IRB meetings. The criteria used for granting approval of the research under the expedited review process are the same as for review by the convened IRB.

7.3.2 VA Central IRB Form 113, Reviewer Checklist for Informed Consent, is also completed for all new project applications. It need only be completed for amendments or continuing reviews if there is a substantive change in the informed consent document or the informed consent process.

7.3.3 During the review, the Expedited Reviewer may contact the investigator directly with any comments or requested modifications. The Expedited Reviewer may also relay any comments or requested modifications to the VA Central IRB Coordinator who can contact the investigator.

7.3.3.1 The investigator is asked to provide any additional information requested by the Expedited Reviewer within five workdays. If the investigator is unavailable, this deadline can be extended at the discretion of the Expedited Reviewer and the VA Central IRB Coordinator. If the action being considered is a continuing review, the expiration date must be taken into consideration as it cannot be extended.

7.3.3.2 The investigator provides copies of any new documentation submitted in response to the Expedited Reviewer's comments to the VA Central IRB Coordinator who provides a copy to the Expedited Reviewer. If the Expedited Reviewer contacted the investigator directly, copies of all communications with the investigator must be forwarded to the VA Central IRB Coordinator via encrypted e-mail, fax, or uploaded to SharePoint to be included in the project file. This process may be repeated as necessary until the Expedited Reviewer is satisfied with the response or the Expedited Reviewer may elect to defer the review to the convened IRB.

7.4 Privacy Officer and Information Security Officer Certifications. For new project applications, the Privacy Officer Representative and the Information Security Officer (ISO) representative on the VA Central IRB each certify that they reviewed the project and it is in compliance with all VA and other privacy, confidentiality, and information security requirements respectively.

7.4.1 The ISO Representative completes the VA Form 122, Information Security Officer (ISO) Compliance Review while the Privacy Officer Representative completes the VA Form 123, Privacy Officer Compliance Review. These completed certifications are provided to the VA Central IRB Coordinator via encrypted e-mail, fax, or uploaded to SharePoint.

7.4.2 If requested by the Expedited Reviewer or Co-Chair, the Privacy Officer and/or Information Security Officer representative provides a new certification for amendments and continuing review reports.

7.4.3 These certifications are should be provided within 10 workdays of receipt. The VA Central IRB Coordinator will follow-up with the Representatives if they are not received within this time frame. Any issues identified must be resolved by the investigator prior to the study being forwarded to the VA Central IRB Co-Chair for final review.

7.5 Actions Taken By the Expedited Reviewer. The Expedited Reviewer makes an approval recommendation within 10 working days of receiving the project action for review unless the Reviewer has questions for the investigator. If questions were forwarded to the investigator, the Expedited Reviewer makes an approval recommendation within five working days of receiving an adequate response from the investigator. The approval recommendation is made on the applicable checklist and forwarded to the VA Central IRB Coordinator, along with the completed VA Central IRB form 121, Expedited Review Eligibility Determination, via an approved method.

7.5.1 For initial review of new project applications, the Expedited Reviewer provides an approval recommendation to the VA Central IRB Co-Chair by selecting one of the following recommended actions:

7.5.1.1 Approval. Changes can be suggested but are not required. The expedited review category or categories under which the expedited review occurred is specified.

7.5.1.2 Modifications Required for Approval. The expedited review category or categories under which the review occurred is specified. The Expedited Reviewer stipulates the specific modifications or clarifications to be made on the reviewer checklist and forwards these to the VA Central IRB Coordinator via an approved method. The VA Central IRB Coordinator then relays these modifications to the investigator via encrypted e-mail, fax, or uploading the information to SharePoint and providing the link to the investigator.

7.5.1.3 Deferral for review by the convened IRB. No further review by the Co-Chair is required. The VA Central IRB Coordinator schedules the project for review at the next regularly scheduled meeting of the VA Central IRB. The Expedited Reviewer serves as the Primary Reviewer at the convened meeting, unless the Expedited Reviewer is unavailable, in which case another voting member is assigned to be the Primary Reviewer by the Co-Chair. A copy of the Expedited Reviewer's comments is included in the materials sent to all VA Central IRB members with the meeting agenda package. If the action pertained to a new project application, a Secondary Reviewer and an Informed Consent Reviewer, if applicable, are also assigned following the procedures set forth in SOP 108, VA Central IRB Meeting Preparation and Administration.

7.5.2 If there are comments submitted by the designated responders at local sites pertaining to the initial approval determination for a new project that require review by the Expedited Reviewer, the VA Central IRB Coordinator will compile these and forward them to the Reviewer after review by the VA Central IRB Administrator.

7.5.2.1 The Expedited Reviewer can give a reason for not accepting a site comment, require additional changes to the project application, require changes to all local site investigator applications, or require changes to a specific local site application. The reasons for not making a change and/or agreeing with a comment(s) and requiring changes will be documented by the Expedited Reviewer on the compiled comment listing.

7.5.2.2 If a change is recommended to the PI/SC Application, the recommendation will be forwarded to the VA Central IRB Co-Chair for the final approval determination regarding the PI/SC New Project Application.

7.5.2.3 No Local Site Investigator Applications are reviewed until all comments from the local sites requiring review are considered and a decision made regarding the comments.

7.5.3 For initial review of Local Site Investigator Applications, the Expedited Reviewer makes one of the approval recommendations specified in paragraph 7.5.1 for each of the local sites. If the Local Site Application is deferred, the Expedited Reviewer will serve as the Primary Reviewer. No additional reviewers will be assigned.

7.5.4 For continuing review of the PI/SC Application, the Expedited Reviewer makes one of the recommendations specified in paragraph 7.5.1 of this SOP with the differences specified below. If an amendment is submitted with the continuing review application, the amendment is considered with the entire application and a separate reviewer checklist for amendments need not be completed by the Reviewer:

7.5.4.1 If the Expedited Reviewer recommends that "Modifications are Required for Approval", the modifications will be relayed to VA Central IRB Administrative Staff who will then forward these, along with any other administrative comments from the Privacy Officer Representative and the Information Security Officer Representative, to the investigator via an approved communication method. The investigator must then ensure the changes are made and submitted to the VA Central IRB Coordinator prior to the expiration of the current approval period. The changes must be submitted with a cover memo detailing the modifications made to include both clean and track change versions of the application and associated documents if applicable.

7.5.4.2 The Expedited Reviewer can also recommend that the project be suspended or a portion of the project be suspended, such as suspending new enrollment only. The reasons for the suspension must be detailed on the reviewer checklist and immediately relayed to the VA Central IRB Coordinator who will immediately notify the VA Central IRB Co-Chair and VA Central IRB Administrator. If

this recommendation is made, the procedures as set forth in VA Central IRB SOP 119, Suspensions and Terminations will be followed.

7.5.4.3 The Expedited Reviewer makes the approval recommendation regarding the Local Site Investigator Applications for the continuing approval after approval of the PI/SC Continuing Review Application by the Co-Chair. The Expedited Reviewer makes an individual recommendation for the continued participation of each of the local participating sites. The Reviewer can recommend one of the following: Approve the site, Require Modifications for Approval, or suspension, or termination of the participation of a site. If suspension or termination is recommended, the reasons for the recommended action are detailed on the reviewer checklist and immediately relayed to the VA Central IRB Coordinator, who will immediately notify the VA Central IRB Co-Chair and VA Central IRB Administrator. The procedures as set forth in VA Central IRB SOP 119 will then be followed.

7.5.5 The Expedited Reviewer, or Primary Reviewer for minor amendments to projects that were reviewed at a convened IRB meeting, makes an approval recommendation to the VA Central IRB Co-Chair. The Reviewer can recommend one of the following: approve the amendment, require modifications for approval, or defer the amendment for review at the convened VA Central IRB. The completed checklist is then forwarded to the VA Central IRB Coordinator.

7.6 Actions Taken by the VA Central IRB Co-Chair. The VA Central IRB Co-Chair serves as the final decision authority under the expedited review process.

7.6.1 Upon receipt of a final recommendation from the Expedited Reviewer, the VA Central IRB Coordinator prepares a VA Central IRB determination letter based on the recommendation of the Expedited Reviewer, and a VA Form 10-1223, Report of Subcommittee on Human Studies for initial reviews, for signature of the VA Central IRB Co-Chair and forwards these to the Co-Chair via an approved method, along with all the applicable documents concerning the action under review and the checklist completed by the Reviewer.

7.6.2 The Co-Chair then reviews the project and ensures the determination being made is consistent with the policies of the VA Central IRB. If the Expedited Reviewer requested modifications, the Co-Chair also reviews these to determine if they are satisfactory. The Co-Chair then completes the Co-Chair portion of the Reviewer Checklist indicated for expedited reviews and takes one of the actions listed below depending upon the type of documentation being reviewed.

7.6.2.1 Approval Contingent upon Receipt and Review of Local Site Comments. This is for use with newly submitted projects only and is used as follows:

7.6.2.1.1 When the project receives a recommendation of "Approved" and no changes are necessary, the Co-Chair can take this action if no further changes are required.

7.6.2.1.2 Once input from all local sites is received and reviewed, the Co-Chair then takes one of the other actions specified below.

7.6.2.2 Approved. No further changes are necessary. The informed consent form, if applicable, is stamped or otherwise dated with the VA Central IRB approval date. For approval of continuing review requests, the continuing review date is based upon the new approval date, which is the date the approval letter is signed by the VA Central IRB Co-Chair.

7.6.2.3 Modifications Required for Approval.

7.6.2.3.1 This is used if, upon review of the response to the request for modifications by the Expedited Reviewer, the Co-Chair is satisfied with the requested modifications. The VA Central IRB Co-Chair can also require additional modifications. The required additional modifications are detailed on the Co-Chairs portion of the Reviewer checklist and the VA Central IRB Coordinator then prepares a new letter to the investigator for the signature of the Co-Chair detailing these modifications. For continuing reviews, all required modifications must be submitted in sufficient time to be reviewed and approved prior to the lapse of the current approval period.

7.6.2.3.2 This is also used for initial PI/SC Applications if, after reviewing any local site comments received and the Expedited Reviewer's recommendation, the Co-Chair determines that additional modifications need to be made.

7.6.2.4 Defer for review by the convened VA Central IRB. The Co-Chair specifies the reasons for deferral on the Reviewer Checklist and the VA Central IRB Coordinator schedules the project for review by the convened IRB in accordance with VA Central IRB SOP 108, Meeting Preparation and Administration.

7.7 Review by the Convened VA Central IRB of Actions Approved Utilizing the Expedited Review Process.

7.7.1 The VA Central IRB Coordinator adds the expedited approval of all new PI/SC New Project Applications, amendments, Local Site Investigator Applications, and continuing reviews to the agenda of the next regularly scheduled meeting of the VA Central IRB. The agenda entry for each project includes: the project title; VA Central IRB number; name of the project; name of PI; LSI as applicable for initial Local Site Investigator Application approvals; type of action; date of approval; and expedited review category under which the action was approved.

7.8.2 The project tracking logs are also updated by each VA Central IRB Coordinator to reflect the date the action was reviewed by the VA Central IRB and the new continuing review expiration date of a project if applicable.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

8.3 45 CFR 46, Department of Health and Human Services, Protection of Human Subjects

8.2 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards

2 Attachments
1. VA Central IRB Form 121, Expedited Review Eligibility Determination
2. Expedited Reviewer Instructions

I have reviewed and approved the content of this SOP.

K. Lynn Cates, MD
Director, PRIDE

Date: 4/21/2010

Expedited Review Eligibility Determination

VA Central IRB
VA Institutional Review Board for Multisite Studies

The VA Central IRB Coordinator completes Sections I, II, III, and IV of this form. A designed VA Central IRB Expedited Reviewer or a VA Central IRB Co-Chair completes Section V.

Section I. Project and Investigator General Information

VA Central IRB#	**Title of Project:**

Type of Documents to Be Reviewed: (One box will be checked)

☐ New Project ☐ LSI Applications ☐ Continuing Review ☐ Amendment #_____

Section II. Expedited Review Category. *(Please check one or more of the following categories that are applicable)*

Categories 1 through 7 can apply to both initial and continuing reviews and should be checked as applicable. Skip to end of this section for amendments.

☐ **Category 1:** Clinical studies of drugs and medical devices only when one of the following conditions is met.

- ☐ **1a:** An investigational new drug application (21 CFR Part 312) or investigational device exemption application (21 CFR Part 812) is not required.
- ☐ **1b:** The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- ☐ **2a:** From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
- ☐ **2b:** From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means.

☐ **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved fro marketing.

☐ **Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

☐ **Category 6:** Collection from voice, video, digital or image recordings made for research purposes.

☐ **Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The following boxes should only be checked for continuing reviews if applicable.

☐ **Category 8:** Research that was previously reviewed by the convened IRB but meets one of the following categories:

- ☐ **Category 8a:** Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects.
- ☐ **Category 8b:** Where no subjects have been enrolled and no additional risks have been identified.
- ☐ **Category 8c:** Where the remaining research activities are limited to data analysis.

☐ **Category 9**: Continuing review of research that was previously reviewed by the convened IRB, that is not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

One of the following boxes must be checked for amendments to currently approved projects only.

☐ The research project for which this modification was submitted was previously approved under the expedited review process. The research continues to pose no more than minimal risk to human participants and the modifications do not involve any procedures that do not meet the expedited review categories 1 through 7 above.

☐ The research project for which this modification was submitted was previously approved by a convened IRB. The modifications do not pose an increased risk to participants and the modifications constitute a minor change to previously approved research.

Section III. Eligibility Determination *(For Initial and Continuing Reviews Only – Skip to Section IV for Amendments)*

☐ The research project presents no more than minimal risk to participants. (The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [38 CFR 16.102(i)].)

☐ The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

☐ The research is not classified or pertain to a vulnerable population not eligible for which VA Central IRB policy does not allow the use of expedited review.

All three boxes must be checked to proceed with expedited review

Section IV. VA Central IRB Coordinator Reviewer Certification

The research project, or amendment as applicable, appears to qualify for expedited review and is being forwarded for an eligibility determination and processing.

_____ _____

VA Central IRB Coordinator Date

Section V. Reviewer Determination ***(Check one of the following boxes)***

☐ I agree that this research project, or amendment as applicable, is eligible for review under the expedited review process and I agree with the category of expedited review as specified by the VA Central IRB Coordinator as designated above.

☐ I agree that this research project, or amendment as applicable, is eligible for review under the expedited review process. However, I do not agree with the category designated above. The eligible category should be Category _____.

☐ The research project does not meet the criteria for expedited review. The project is being returned and should be processed as *(Check one)* ☐ Exempt ☐ Review by Convened Board ☐ Other

Comments:

_____ _____

Signature of VA Central IRB Reviewer Date

Expedited Reviewer Instructions

VA Central IRB
VA Institutional Review Board for Multisite Studies

The attached materials are have been uploaded to SharePoint for review under the expedited review process.

☐ **VA Central IRB Form 108, Principal Investigator New Project Application, with attachments**

☐ **VA Central IRB 104, Local Site Investigator Application(s) with attachments and document comparison table**

☐ **VA Central IRB Forms 115a and 115b, Application for Continuing Review for both PI/SC and Local Sites, comparison table, and list of documents for review**

☐ **VA Central IRB Form 116, Request to Amend an Approved Project, with attachments**

Instructions for Reviewers

1. A VA Central IRB Form 121, Expedited Review Eligibility Determination, has also been uploaded to SharePoint. This form needs to be completed prior to performing the in-depth review of the documents to determine if the project qualifies for expedited review. Most of the form has already been completed by the VA Central IRB Coordinator. You will need to verify the category assignment, change, it, or otherwise complete the form by signing and dating it.

2. If eligible for expedited review, please complete and sign the checked reviewer checklists, which have also been uploaded to SharePoint.

☐ **VA Central IRB Form 111a, Reviewer Checklist for PI New Project Application**

☐ **VA Central IRB Form 111b, Reviewer Checklist for Local Site Investigator Applications**

☐ **VA Central IRB Form 113, Reviewer Checklist for Informed Consent**

☐ **VA Central IRB Form 114a, Continuing Reviewer Checklist for Local Site Investigator Applications**

☐ **VA Central IRB Form 114b, Reviewer Checklist for Continuing Review (PI/SC Application)**

☐ **VA Central IRB Form 120, Reviewer Checklist for Amendments**

3. If you, as the Expedited Reviewer, have a conflict of interest, immediately indicate this on the reviewer checklist. Then sign and return the form to the VA

Central IRB Coordinator. It can be scanned and uploaded to SharePoint or sent via fax or encrypted e-mail.

4. Reviewers may contact investigators directly if they have any questions or concerns or they may relay these questions or concerns to the VA Central IRB Administrative Office, who will contact the investigator for a response.

5. Reviewers are asked to complete the review within 10 working days, or five working days after a response is received from an investigator to any questions forwarded previously. If something comes up and you cannot complete the review, please contact the VA Central IRB Administrative Office immediately to ask that it be re-assigned.